REMARKS/ARGUMENTS

Claims 1-5, 7-12, 14-18, 20 and 21 are pending in this application. Claims 6, 13, and 19 have been previously canceled.

Claims 1, 7 and 14 have been amended to require a microparticle size between about 10 microns and about 20 microns in diameter wherein more than 50% of the microparticles have a particle size greater than about 10 microns. Support for these amendments can be found in the specification in, *inter alia*, paragraph 0013 and in Examples 1 and 2. No new matter has been introduced as a result of the claim amendments.

By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

35 U.S.C. §103 Rejections

It is well established that a *prima facie* case of obviousness requires that the Office provide evidence to support three basic criteria: there must be some suggestion or motivation in the cited art to modify a reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references must teach or suggest all the claim limitations. MPEP 2143. Furthermore, where one reference is relied upon by the Examiner, there must be a suggestion or motivation to modify the teachings of that reference. See *In re Kotzab*, 55 U.S.P.Q.2d 1316 (Fed. Cir. 2000).

Claims 1, 2, 4, 5, 7, 9, 11, 12, 14, 15, 17 and 18 are rejected under 35 USC §103(a) as being unpatentable over Steiner et al. (U.S. Patent No. 5,503,852). Applicants respectfully disagree.

The instant claims, as amended, recite microparticles between about 10 microns and about 20 microns in diameter wherein more than 50% of the microparticles have a particle size greater than about 10 microns.

Steiner discloses particles between 0.1 to 10 microns in diameter. Steiner does not disclose microparticles wherein more than 50% of the microparticles have a particle size greater than about 10 microns. The microparticles of Steiner are primarily used for delivery to the pulmonary system, a use requiring smaller particles. In paragraph 0008 of the instant specification, Applicants state "[a] critical aspect is the size range of the microparticles, between approximately 10 and 20 microns in diameter, which causes the particles to be retained in the nasal region, and not passed into the pulmonary system or mouth." Therefore, Steiner does not teach or suggest microparticles wherein the majority of the particles are greater that 10 microns in size and furthermore, Steiner does not suggest that larger particles are necessary to be retained in the nasal cavity.

The Office asserts on page 6, lines 10-11 of the Office Action mailed November 16, 2008 that "[a]bsent a showing of evidence to the contrary, Steiner's microparticles would be suitable for nasal administration." In Example 3 of the instant specification, three volunteers were dosed with the claimed nasal composition and two of the three volunteers did not detect any bitter taste associated with the nasal-administered dry powder, indicating that the particles were retained in the nose and did not pass into the mouth. This experiment confirms Applicants earlier statements that the larger particles (10 to 20 microns in size) are retained in the nasal cavity (as opposed to the mouth or lungs) as evidenced by the lack of taste due to the presence of particles in the mouth. The smaller particles of Steiner would pass through the nasal cavity into the mouth and lungs and therefore do not disclose the presently claimed invention.

As demonstrated *supra*, Steiner does not teach or suggest all of the limitations of independent claims 1, 7 and 14 and dependent claims 2, 4, 5, 9, 11, 12, 15, 17 and 18, namely microparticles between about 10 microns and about 20 microns in diameter wherein more than 50% of the microparticles have a particle size greater than about 10 microns. Applicants therefore respectfully request the withdrawal of the 35 USC §103(a) rejection on this basis.

Claims 3, 8, 10, 16, 20 and 21 are rejected under 35 USC §103(a) as being unpatentable over Steiner et al. (U.S. Patent No. 5,503,852) as applied to claims 1, 2, 4,

5, 7, 9 11, 12, 14, 15, 17, and 18 and further in view of Illum (U.S. Patent No. 5,690,954). Applicants respectfully disagree.

Steiner has been discussed *supra*. Illum teaches drug delivery systems comprising microsphere particles containing an active drug and a bioavailability enhancer. Illum states that the microspheres should be of a size between 10 and 100 microns (column 6, lines 13-14). In column 6, line 28 through column 7, line 54, Illum presents examples of microspheres and their sizes. Starch microspheres were prepared having a mean size of 33 microns (column 6, lines 52-53); albumin microspheres were prepared having a size range of 40-60 microns (column 7, lines 1-2) and a mean size of 43 ± 6 microns (column 7, lines 19-20); gelatin microspheres were prepared having a mean particle size of 70 microns (column 7, lines 30-31) and 60 microns (column 7, lines 41-42); and chitosan microspheres were prepared having a size range of 10-90 microns (column 7, lines 53-54). While Illum teaches microspheres made from a variety of materials, none of the materials produced microparticles in which the majority of the microparticles are in the range of 10-20 microns. In fact, the majority of the microspheres produced by Illum are greater than 20 microns in size, teaching away from the instant claims which recite microparticles of 10-20 micron size as optimal for effective delivery of drugs to the nasal mucosa.

While there is overlap in the range of the claimed microparticles and the microspheres of Illum, Illum does not teach or suggest microparticles between about 10 microns and about 20 microns in diameter wherein more than 50% of the microparticles have a particle size greater than about 10 microns.

As demonstrated *supra*, Steiner and Illum, in combination, do not teach or suggest all of the limitations of independent claims 1, 7 and 14 and dependent claims 2, 4, 5, 9, 11, 12, 15, 17 and 18, namely microparticles between about 10 microns and about 20 microns in diameter wherein more than 50% of the microparticles have a particle size greater than about 10 microns. Applicants therefore respectfully request the withdrawal of the 35 USC §103(a) rejection on this basis.

Conclusion

In light of the claim amendments and arguments presented supra, Applicant respectfully asserts that the pending claims are in condition for allowance and that a timely Notice of Allowance be issued in this case.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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